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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/807,504	12/17/2001	Ryszard Kobylecki	687-94	9353

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EXAMINER	
TRAN, MY CHAU T	
ART UNIT	**PAPER NUMBER**
1639	

DATE MAILED: 08/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/807,504	KOBYLECKI, RYSZARD	
	Examiner	Art Unit	
	MY-CHAU T TRAN	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 May 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *38,40-43,47-58 and 75-88* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *38,40-43,47-58 and 75-88* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/4/04 has been entered.

Status of Claims

2. Claims 38 was amended and Claims 83-88 were added by the amendment filed on 12/4/03.

3. Claims 1-37, 39, 44-46, and 59-74 were canceled, Claims 38, 48, and 53-54 were amended, and Claims 75-82 were added by the amendment filed on 7/8/03.

4. Claims 38, 40-43, 47-58, and 75-88 are pending.

5. This application is a 371 of PCT/GB99/03406 filed 10/14/1999, which claims priority to a foreign application United Kingdom 9822436.3 filed 10/14/1998.

6. Applicant has elected the following species for the elected invention (Claims 38, 40-43, 47-58, and 75-88) in the reply filed on 5/20/04:

a. A species of active material. Applicant hereby elects formyl polystyrene.

7. Claims 38, 40-43, 47-58, and 75-88 are treated on the merit in this Office Action.

Claim Objections

8. Claim 83 objected to under 37 CFR 1.75 as being a substantial duplicate of claim 57. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 38, 40-43, 47-58, and 75-88 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 38 and 75 recites a "method of synthesis". However, the type of product that is produced by the method is not set forth. The claimed "*method of synthesis comprises the step of contacting said porous device with a first reagent under conditions which cause said first reagent to react with said active material, so that a bond is formed between the active material and said first reagent or a fragment thereof.*" Thus it is unclear what constitutes the metes and bounds what is being produced by this method (i.e. a functionalized resin or a compound bound

to the resin). It is suggested that applicant amend the claims 38 and 75 to "A method of synthesis of an active resin" or "A method of synthesis of a compound attached to the resin".

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

12. Claims 38, 47-48, 51-54, 56, 58, 75-76, 78, and 81-82 are rejected under 35 U.S.C. 102(a) as being anticipated by Sucholeiki et al. (US Patent 5,834,121).

Sucholeiki et al. discloses a composite magnetic bead (porous device) and using the composite magnetic bead for organic synthesis (Abstract; col. 2, lines 30-42). The composite magnetic bead comprises a matrix (internal region) throughout which are distributed primary beads (active material/resin) (col. 2, lines 43-51). The mesh or matrix comprising of a thermoplastic polymer resin that is microporous, and which is capable of swelling or expanding in organic solvent, wherein the primary beads are randomly distributed throughout the matrix (refers to claims 47, 51, 53-54, and 81-82). The matrix encapsulated the primary bead, which is interpreted as "*held in position by a physical weld*" (col. 2, lines 66-67). The composite bead is essentially spherical in shape and has an uneven, undulating surface (col. 2, lines 43-51). The bead would provides a support system which retains its magnetic properties, has a high loading capacity, and maintains availability of reaction sites, even though it swells and contracts depending upon the solvent and temperature conditions to which it is exposed (col. 2, lines 23-

42). The volume of the composite magnetic bead is 0.7 ml (i.e. 700 mm^3) (refers to claim 78). Sucholeiki et al. also disclose using these beads as support for chemical synthesis wherein the first reagent is affixed to a magnetizable bead (col. 1, line 49 to col. 2, line 11; col. 2, lines 40-42). Thus the method of Sucholeiki et al. anticipates the presently claimed invention.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

15. Claims 38, 40-43, 47-58, 75-84, and 86-88 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dower et al. (US Patent 5,770,358) and Sucholeiki et al. (US Patent 5,834,121).

Dower et al. disclose a method for synthesizing synthetic oligomer (Abstract; col. 4, lines 66-67). The method comprise of a single oligomer sequence (first reagent) being bound to a solid support (active material) by means of a linker (col. 8, lines 48-67 to col. 9, lines 1-14). The solid support comprise of materials such as colloidal metal particles or cross-linked polystyrene (resin) (col. 11, lines 31-45). The method also includes the step of cleaving the compound from the support (col. 12, lines 26-28) (refers to claim 43).

The method of Dower et al. does not expressly disclose that the solid support (active material) is entrapped within a porous support and the porous support is a thermoplastic inert material.

Sucholeiki et al. discloses a composite magnetic bead (porous device) and using the composite magnetic bead for organic synthesis (Abstract; col. 2, lines 30-42). The composite magnetic bead comprises a matrix (internal region) throughout which are distributed primary beads (active material/resin) (col. 2, lines 43-51). The mesh or matrix comprising of a thermoplastic polymer resin that is microporous, and which is capable of swelling or expanding in organic solvent, wherein the primary beads are randomly distributed throughout the matrix (refers to claims 47, 51, 53-54, and 81-82). The matrix encapsulated the primary bead, which is interpreted as "*held in position by a physical weld*" (col. 2, lines 66-67). The composite bead is essentially spherical in shape and has an uneven, undulating surface (col. 2, lines 43-51). The bead would provides a support system which retains its magnetic properties, has a high loading capacity, and maintains availability of reaction sites, even though it swells and contracts depending upon the solvent and temperature conditions to which it is exposed (col. 2, lines 23-42). The volume of the composite magnetic bead is 0.7 ml (i.e. 700 mm^3) (refers to claim 78).

Sucholeiki et al. also disclose using these beads as support for chemical synthesis wherein the first reagent is affixed to a magnetizable bead (col. 1, line 49 to col. 2, line 11; col. 2, lines 40-42). Additionally with regard to claims 80, and 86-87, the limitation of the weight percent of material comprising the porous device would be a choice of experimental design and is considered within the purview of the cited prior art.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include the solid support (active material) is entrapped within a porous support and the porous support is a thermoplastic inert material as taught by Sucholeiki et al. in the method of Dower et al. One of ordinary skill in the art would have been motivated to include the solid support (active material) is entrapped within a porous support and the porous support is a thermoplastic inert material in the method of Dower et al. for the advantage of providing a support system that has a high loading capacity and maintains availability of reaction sites for chemical synthesis where rapid separation of products from reactants in solution is desired (Sucholeiki: col. 2, lines 23-42). Furthermore, one of ordinary skill in the art would have reasonably expectation of success in the combination of Dower et al. and Sucholeiki et al. since both Dower et al. and Sucholeiki et al. disclose the method of solid phase synthesis wherein the first reagent is attached to a bead such as the colloidal metal particles of Dower et al. and the magnetizable bead of Sucholeiki et al. (Dower: col. 8, lines 48-67 to col. 9, lines 1-14; Sucholeiki: col. 1, line 49 to col. 2, line 11; col. 2, lines 40-42; col. 3, lines 49-59). Thus there is a reasonably expectation of success in the combination of Dower et al. and Sucholeiki et al.

16. Claim 85 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dower et al. (US Patent 5,770,358) and Sucholeiki et al. (US Patent 5,834,121) as applied to claims 38, 40-43, 47-58, 75-84, and 86-88 above, and further in view of Hu et al. (US Patent 6,147,159).

Dower et al. disclose a method for synthesizing synthetic oligomer (Abstract; col. 4, lines 66-67). The method comprise of a single oligomer sequence (first reagent) being bound to a solid support (active material) by means of a linker (col. 8, lines 48-67 to col. 9, lines 1-14). The solid support comprise of materials such as colloidal metal particles or cross-linked polystyrene (resin) (col. 11, lines 31-45). The method also includes the step of cleaving the compound from the support (col. 12, lines 26-28) (refers to claim 43).

Sucholeiki et al. discloses a composite magnetic bead (porous device) and using the composite magnetic bead for organic synthesis (Abstract; col. 2, lines 30-42). The composite magnetic bead comprises a matrix (internal region) throughout which are distributed primary beads (active material/resin) (col. 2, lines 43-51). The mesh or matrix comprising of a thermoplastic polymer resin that is microporous, and which is capable of swelling or expanding in organic solvent, wherein the primary beads are randomly distributed throughout the matrix (refers to claims 47, 51, 53-54, and 81-82). The matrix encapsulated the primary bead, which is interpreted as "*held in position by a physical weld*" (col. 2, lines 66-67). The composite bead is essentially spherical in shape and has an uneven, undulating surface (col. 2, lines 43-51). The bead would provides a support system which retains its magnetic properties, has a high loading capacity, and maintains availability of reaction sites, even though it swells and contracts depending upon the solvent and temperature conditions to which it is exposed (col. 2, lines 23-42). The volume of the composite magnetic bead is 0.7 ml (i.e. 700 mm^3) (refers to claim 78).

Sucholeiki et al. also disclose using these beads as support for chemical synthesis wherein the first reagent is affixed to a magnetizable bead (col. 1, line 49 to col. 2, line 11; col. 2, lines 40-42). Additionally with regard to claims 80, and 86-87, the limitation of the weight percent of material comprising the porous device would be a choice of experimental design and is considered within the purview of the cited prior art.

The method combination of Dower et al. and Sucholeiki et al. disclose the method of synthesis wherein the method step comprises attaching a first reagent to a bead and the bead is entrapped in a matrix as discussed in the rejection under 35 USC 103(a) as being unpatentable over Dower et al. (US Patent 5,770,358) and Sucholeiki et al. (US Patent 5,834,121) for claims 38, 40-43, 47-58, 75-84, and 86-88. However, the method combination of Dower et al. and Sucholeiki et al. do not expressly disclose the bead that comprises of formyl polystyrene.

Hu et al. discloses a modified solid support for use in solid phase synthesis (Abstract; col. 2, lines 66-67). The solid support comprises materials such as organic polymer resins that include functionalized polystyrenes such as formyl polystyrene (col. 12, lines 60-67; col. 13, lines 39-49). Hu et al. discloses several methods for attaching substituents onto the solid support (col. 4, lines 42-52). The method comprises the steps of taking the solid support with an alkene (linker) and reacting it with a silane (first reagent) to form a bond.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include the bead that comprises of formyl polystyrene as taught by Hu et al. in the method combination of Dower et al. and Sucholeiki et al. One of ordinary skill in the art would have been motivated to include the bead that comprises of formyl polystyrene in the method combination of Dower et al. and Sucholeiki et al. since the type of bead would be a

choice of experimental design and is considered within the purview of the cited prior art. Furthermore, one of ordinary skill in the art would have reasonably expectation of success in the combination of Dower et al., Sucholeiki et al., and Hu et al. because Dower et al., Sucholeiki et al. and Hu et al. disclose the method of solid phase synthesis wherein the first reagent is attached to a bead (Dower: col. 8, lines 48-67 to col. 9, lines 1-14; Sucholeiki: col. 1, line 49 to col. 2, line 11; col. 2, lines 40-42; col. 3, lines 49-59; Hu: col. 4, lines 42-52). Thus there is a reasonably expectation of success in the combination of Dower et al., Sucholeiki et al. and Hu et al.

17. Claims 38, 40-43, 47-58, 75-84, and 86-88 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sucholeiki et al. (US Patent 5,684,130) and Sucholeiki et al. (US Patent 5,834,121).

Sucholeiki et al. (US Patent 5,684,130) the method of synthesis of a defined chemical entity, i.e., any desired chemical compound using a solid resin support on which the synthesis occurs (Abstract; col. 1, lines 5-12; col. 4, lines 10-15 and 28-31). The solid support includes polymer resin and magnetic bead (col. 5, lines 7-37). The method of synthesis comprises a sequence of steps that would produce the desired chemical entity in its final form (col. 6, lines 36-58). The sequence of steps includes the step of coupling the first reagent to the solid support. Additionally, the step includes derivatizing the support with functional groups (linker) (refers to claim 42). Additionally, the method includes the step of cleaving the chemical entity from the support (col. 6, lines 52-56) (refers to claim 43).

The method of Sucholeiki et al. (US Patent 5,684,130) does not expressly disclose that the solid support (active material) is entrapped within a porous support and the porous support is a thermoplastic inert material.

Sucholeiki et al. (US Patent 5,834,121) discloses a composite magnetic bead (porous device) and using the composite magnetic bead for organic synthesis (Abstract; col. 2, lines 30-42). The composite magnetic bead comprises a matrix (internal region) throughout which are distributed primary beads (active material/resin) (col. 2, lines 43-51). The mesh or matrix comprising of a thermoplastic polymer resin that is microporous, and which is capable of swelling or expanding in organic solvent, wherein the primary beads are randomly distributed throughout the matrix (refers to claims 47, 51, 53-54, and 81-82). The matrix encapsulated the primary bead, which is interpreted as "*held in position by a physical weld*" (col. 2, lines 66-67). The composite bead is essentially spherical in shape and has an uneven, undulating surface (col. 2, lines 43-51). The bead would provides a support system which retains its magnetic properties, has a high loading capacity, and maintains availability of reaction sites, even though it swells and contracts depending upon the solvent and temperature conditions to which it is exposed (col. 2, lines 23-42). The volume of the composite magnetic bead is 0.7 ml (i.e. 700 mm^3) (refers to claim 78). Sucholeiki et al. also disclose using these beads as support for chemical synthesis wherein the first reagent is affixed to a magnetizable bead (col. 1, line 49 to col. 2, line 11; col. 2, lines 40-42). Additionally with regard to claims 80, and 86-87, the limitation of the weight percent of material comprising the porous device would be a choice of experimental design and is considered within the purview of the cited prior art.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include the solid support (active material) is entrapped within a porous support and the porous support is a thermoplastic inert material as taught by Sucholeiki et al. (US Patent 5,834,121) in the method of Sucholeiki et al. (US Patent 5,684,130). One of ordinary skill in the art would have been motivated to include the solid support (active material) is entrapped within a porous support and the porous support is a thermoplastic inert material in the method of Sucholeiki et al. (US Patent 5,684,130) for the advantage of providing a support system that has a high loading capacity and maintains availability of reaction sites for chemical synthesis where rapid separation of products from reactants in solution is desired (Sucholeiki: col. 2, lines 23-42). Furthermore, one of ordinary skill in the art would have reasonably expectation of success in the combination of Sucholeiki et al. (US Patent 5,684,130) and Sucholeiki et al. (US Patent 5,834,121) because Sucholeiki et al. (US Patent 5,834,121) incorporated the method of Sucholeiki et al. (US Patent 5,684,130) by reference (col. 1, lines 49-52).

Withdrawn Rejections

18. The rejection of claims 38, 40-43, 47-58 and 76-82 under 35 USC 112, first paragraph (written description) has been withdrawn in light of applicant's arguments, see pg. 10, lines 3-7, filed 12/4/03.

19. The rejection of claims 38, 40-43, 47-56, 58, 76-77, 79, and 81-82 under 35 USC 102(b) as being anticipated by BIOSEPRA INC. (WO 98/41534) has been withdrawn in light of applicant's arguments, see pg. 12, lines 14-19, filed 12/4/03.

Response to Arguments

20. Applicant's arguments directed to the rejection under 35 USC 103(a) as being unpatentable over Dower et al. (US Patent 5,770,358) and Sucholeiki et al. (US Patent 5,834,121) for claims 38, 40-43, 47-58, and 75-82 were considered but they are not persuasive for the following reasons.

Applicant contends that the combination of Dower et al. and Sucholeiki et al. is not obvious over claim 75 because neither Dower et al. nor Sucholeiki et al. describe or suggest a reaction with an active material of the type described in claim 75, and there is no motivation to combine Dower et al. and Sucholeiki et al. to arrive at the combination of claim 75. Therefore, the combination of Dower et al. and Sucholeiki et al. is not obvious over claim 75.

Applicant's arguments are not convincing since the combination of Dower et al. and Sucholeiki et al. is obvious over claim 75. The claimed reaction with an active material described in claim 75, i.e. "*the method of synthesis including the step of contacting said porous device with a first reagent under conditions which cause said first reagent to react with said active material, so that a bond is formed between the active material and said first reagent or a fragment thereof*" is describes or suggested by both Dower et al. and Sucholeiki et al. Both Dower et al. and Sucholeiki et al. disclose the method of solid phase synthesis wherein the first reagent is attached to a bead such as the colloidal metal particles of Dower et al. and the magnetizable bead of Sucholeiki et al. (Dower: col. 8, lines 48-67 to col. 9, lines 1-14; Sucholeiki: col. 1, line 49 to col. 2, line 11; col. 2, lines 40-42; col. 3, lines 49-59). Since both Dower et al. and Sucholeiki et al. disclose the method of solid phase synthesis, i.e., analogous art

there is a motivation to combine. Furthermore, the combination of Dower et al. and Sucholeiki et al. would provide the advantage of a support system that has a high loading capacity and maintains availability of reaction sites for chemical synthesis where rapid separation of products from reactants in solution is desired as disclosed by Sucholeiki et al. (col. 2, lines 23-42). Thus the combination of Dower et al. and Sucholeiki et al. is obvious over claim 75 and the rejection is maintained.

Additionally, since this rejection also include the independent claim 38, and applicant did not present any argument(s) with regard to the independent claim 38 this rejection is also maintained for claims 38, 40-43, 47-58, and 76-82.

21. Applicant submitted the website advertisement of the commercial sale of the porous device, i.e. StratoSpheres™, as objective evidence of commercial success. The evidence is not considered because 1) it is improperly provided without a proper affidavits or declarations (see MPEP § 716.01(a)); 2) there is ***no nexus*** between the presently claimed invention, i.e. a method of synthesis, and the commercial sale of the porous device, i.e. StratoSpheres™; and 3) the website advertisement of the commercial sale is ***not*** comparative data of commercial success. Thus the website advertisement of the commercial sale is not consider objective evidence of commercial success and objective evidence of nonobviousness.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MY-CHAU T TRAN whose telephone number is 571-272-0810.

The examiner can normally be reached on Mon.: 8:00-2:30; Tues.-Thurs.: 7:30-5:00; Fri.: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANDREW WANG can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mct
August 5, 2004

PADMASHRI PONNALURI
PRIMARY EXAMINER